DEC 0 7 2001

K013031
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510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics MOST Options™ System

Manufacturer:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	September 7, 2001
Contact Person:	Frances E. Harrison, RAC Senior Regulatory Affairs Specialist
Classification Name:	Knee joint femorotibial metal/polymer constrained cemented prosthesis - 21 CFR Part 888.3510 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis - 21 CFR Part 888.3353
Common/Usual Name:	Total Hinged Knee for Total Knee Replacement Femorotibial Prosthesis
Trade/Proprietary Name:	MOST Options™ System (MOST)

PRODUCT DESCRIPTION

The MOST Options System (MOST) is used for the replacement of the proximal, distal or total femur and/or the proximal tibia. Replacement of the distal femur would also include replacement of the proximal tibia and possible resurfacing of the patella, if necessary. Unlike primary hip and knee systems, this system can be used where extensive femoral and/or tibial resection and restoration is required (e.g., oncology cases). Modularity of the system allows for the resection of varying amounts of the femur and the proximal tibia (and patella, if necessary) before implantation. A total replacement is possible in cases where no part of the femur can be salvaged. Moreover, the system provides additional options for revision or severe bone loss of the tibia. The components of the MOST System include:

- a distal femoral replacement (Condylar End or Hinged Femur) which mates with a tibial component via a hinge type mechanism (Hinge-Kit or 4mm Hinge Kit);
- a proximal femur replacement that is available in two designs to address the presence or absence of the greater trochanter;
- intramedullary (I/M) stems with Cancellous Structured Titanium™ (CSTi™) and MOST segments which will be used in conjunction with the proximal and distal femoral replacements, the Proximal Tibia and the MOST Revision Stem Adapter;
- an all poly patella;

- a proximal tibia replacement (Proximal Tibia or Hinged Tibia) which mates with the Proximal Tibia Insert and Hinged Tibia Insert, respectively and features a distal female taper for attachment of a MOST Revision Stem Adapter, Sulzer Revision Stems or Hinged Tibia Stem Plug (Hinged Tibia only);
- femoral and tibial spacers for use in conjunction with the Hinged Femur and Hinged Tibia, respectively to augment uni-compartmental or bi-compartmental defects; and
- revision stem adapter with and without CSTi coating used to convert the MOST taper to the Sulzer taper.

SPECIFIC DIAGNOSTIC INDICATIONS

Components of the MOST System are intended to replace the proximal, distal or total femur and/or the proximal tibia, especially in cases that require extensive resection and restoration. Specific diagnostic indications for use of the MOST include:

- metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) and trauma requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur and/or proximal tibia;
- patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and inflammatory (IJD), e.g. rheumatoid arthritis, requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur and/or proximal tibia; and
- revision cases requiring resection(s) and replacement(s) of the proximal, distal or total femur and/or proximal tibia.

SUBSTANTIAL EQUIVALENCE

The MOST Options System is similar to the following commercially available devices in terms of materials, general design features, and intended uses:

- Sulzer Orthopedics MOST™ System
- Johnson & Johnson S-ROM® Noiles™ Rotating Hinge Knee System
- Howmedica Osteonics® Modular Rotating Hinge Knee (MRS)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 7 2001

Ms. Frances E. Harrison, RAC
Senior Regulatory Affairs Specialist
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K013031
Trade/Device Name: MOST Options System
Regulation Number: 21 CFR 888.3510; 21 CFR 888.3353
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis; Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: KRO, LZO
Dated: September 7, 2001
Received: September 10, 2001

Dear Ms. Harrison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013031

Device Name: MOST System

Indications for Use:

The MOST System is intended to replace the proximal, distal or total femur and/or the proximal tibia, especially in cases that require extensive resection and restoration. Replacement of the distal femur would also include replacement of the proximal tibia and possible resurfacing of the patella, if necessary. Proximal femoral replacement components are available for press-fit or cemented applications. Components used for replacement of the distal femur and proximal tibia are intended for cemented use only. Specific diagnostic indications for use of the MOST include:

1. metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur and/or proximal tibia;

2. patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and inflammatory (IJD), e.g. rheumatoid arthritis, requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur and/or proximal tibia; and

3. revision cases requiring resection(s) and replacement(s) of the proximal, distal or total femur and/or proximal tibia.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of Ge[illegible]
and Neurologic[illegible]

510(k) Number K013031

Prescription Use X **OR** **Over-the Counter Use** ____

(Optional Format 1-2-96)